IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CHARLES LEON MANOUS, Surviving Spouse and Personal Representative of the Estate of CAROL ANN MANOUS, deceased,	)	
Plaintiff,	)	
vs.	)	Case No. 11-cv-1330-R
MYLAN PHARMACEUTICALS, INC.,	)	
Defendant.	)	

A M E N D E D C O M P L A I N T

JURISDICTION AND VENUE

1. Defendant is subject to the jurisdiction of this Court and venue is proper because a substantial part of the events leading to CAROL ANN MANOUS's wrongful death occurred in McClain County, Oklahoma, which is within the Western District of Oklahoma.

2. Mylan Pharmaceuticals, Inc. is a foreign, for profit, business corporation which has been ousted from the State of Oklahoma.

3. Mylan Pharmaceuticals, Inc. may be served through its registered service agent: (1) Corporation Service Company, 115 S.W. 89th St., Oklahoma City, OK 73139; or, (2) Corporation Service Company, 209 W. Washington St., Charleston, WV 25302.

CAUSE OF ACTION

4. MYLAN PHARMACEUTICALS, INC. manufactures, markets, sells, and distributes the Fentanyl Transdermal System [hereinafter Fentanyl Transdermal System or

Product].

5. The Fentanyl Transdermal System is a device which delivers a predetermined amount of a pharmaceutical compound known as Fentanyl to a patient over a period of time.

6. The Fentanyl Transdermal System is intended for use in the treatment of pain.

7. On or about March 12, 2010, CAROL ANN MANOUS was using the Fentanyl Transdermal System, which was manufactured, distributed, marketed and sold by Defendant MYLAN PHARMACEUTICALS, INC.

8. Said Fentanyl Transdermal System was defective, delivered excessive amounts of Fentanyl to CAROL ANN MANOUS, and caused CAROL ANN MANOUS's death.

9. The Board of Medicaolegal Investigations's Report of Laboratory Analysis shows that CAROL ANN MANOUS had a blood concentration of Fentanyl of 28.1 ng/ml.

10. A blood concentration of Fentanyl of 28.1 ng/ml is vastly in excess of the amount of Fentanyl that would have been delivered via a non-defective Fentanyl Transdermal System.

11. A blood concentration of Fentanyl of 28.1 ng/ml is vastly in excess of the mean maximum concentration of Fentanyl that is delivered via the Fentanyl Transdermal System according to documents which Defendant MYLAN PHARMACEUTICALS, INC. has submitted to the United States Food and Drug Administration.

12. The design characteristics of Defendant's Fentanyl patches is such that when they have been manufactured without defects, the serum Fentanyl concentrations resulting

from a 100 mcg patch should not exceed approximately 5 ng/ml.

13. Mrs. Manous died as a result of an overdose of Fentanyl delivered by Defendant's defective patch.

14. The medical examiner's report shows that the specific level of Fentanyl in Mrs. Manous's blood was 28.1 ng/ml.

15. The characteristics of the subject patches, which delivered a dosage which achieved a level of 28.1 ng/ml rendered the Defendant's Fentanyl patches defective because they delivered a dosage substantially in excess of their intended design.

16. Defendant Mylan Pharmaceuticals, Inc.'s Fentanyl patches should have delivered a therapeutic, pain-relieving level of less than 5 ng/ml of Fentanyl each to Mrs. Manous. That is the information which Defendant Mylan Pharmaceuticals, Inc. provides in its package inserts.

17. Instead, the Fentanyl patches at issue delivered a fatal dosage which reached a level of 28.1 ng/ml, surprisingly more than the designed dosage.

18. Defendant's patches were defective and unreasonably dangerous. They delivered excessive amounts of Fentanyl in comparison to non-defective Fentanyl patches. They delivered excessive amounts of Fentanyl which were vastly more dangerous than would be contemplated by an ordinary consumer of the patches. They delivered excessive amounts of Fentanyl in comparison to the data supplied by Defendant Mylan Pharmaceuticals, Inc. to the United States Food and Drug Administration.

19. Far from being safe and effective, a position taken by Defendant Mylan Pharmaceuticals, Inc. in its FDA filings, the Fentanyl patches killed Mrs. Manous.

20. In the case at bar, neither Mrs. Manous nor her physician were provided adequate warnings and information to apprize them about the dangers of the product.

21. To the contrary, Defendant Mylan Pharmaceuticals, Inc. misled the physician and the patient about the dosage which the product would deliver.

22. Defendant MYLAN PHARMACEUTICALS, INC.'s Product was in a defective condition which was unreasonably dangerous to the user, for which Defendant is strictly liable.

23. Defendant MYLAN PHARMACEUTICALS, INC. is in the business of manufacturing and selling pharmaceuticals in general and this Product in particular.

24. Defendant MYLAN PHARMACEUTICALS, INC. failed to warn CAROL ANN MANOUS of risks known to Defendant MYLAN PHARMACEUTICALS, INC. about the Product.

25. Defendant MYLAN PHARMACEUTICALS, INC. failed to warn CAROL ANN MANOUS's physicians of risks known to Defendant MYLAN PHARMACEUTICALS, INC. about the Product.

26. Defendants failed to warn or inform the United States Food and Drug Administration of risks known to Defendant MYLAN PHARMACEUTICALS, INC. about the Product.

27. Defendants failed to warn or inform the public of risks known to Defendant MYLAN PHARMACEUTICALS, INC. about the Product.

28. Numerous claims have been made by those persons physically injured by Defendant's Product and those claims have brought awareness of the defects to Defendant.

29. The Product was not reasonably fit for the ordinary purpose for which it was reasonably expected to be used because the Product was defective and dangerous to an extent beyond that which would be contemplated by the ordinary user or consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics.

30. The Product was unreasonably dangerous to a person who uses, consumes, or might be reasonably expected to be affected by the product.

31. The Product was defective at the time it was manufactured and sold by Defendant.

32. Mrs. Manous recieved the product in sealed containers which had remained undisturbed since the time they were sealed by the Defendant.

33. Plaintiff was a person who used, consumed, or could have reasonably been affected by the Product.

34. Defendants acted intentionally and with malice, or in the alternative, with reckless disregard for the rights of others and with gross negligence. The Defendant's conduct in this case recklessly endangered CAROL ANN MANOUS and the public in general in such a manner as to warrant the imposition of punitive damages.

35. CAROL ANN MANOUS would not have died if Defendant's Product had not been defective.

36. CAROL ANN MANOUS is survived by her surviving husband, CHARLES LEON MANOUS, by her children, Bo Tucker and Logan Manous, and by her father, Carl Franklin.

PRAYER FOR RELIEF

37. WHEREFORE, Plaintiff prays as follows:

a) That process issue and that Defendant be served as provided by law;

b) That Plaintiff recover judgment for medical and burial expenses, loss of consortium and grief of the surviving spouse, mental pain and anguish suffered by the decedent, and grief and loss of companionship of the surviving children and parent of the decedent, in excess of the Federal jurisdictional amount of seventy-five thousand dollars ($75,000.00), plus punitive damages;

c) That Plaintiff have judgment against Defendant in an amounts to be determined upon the evidence, and other damages determined upon the evidence by the enlightened conscience of the fact finder;

d) That all costs of this action be cast against Defendant; and

e) That Plaintiff have such other and further relief as this Court deems just and proper.

NORMAN & EDEM, P.L.L.C.

By:/s/ L. Mark Bonner

Emmanuel E. Edem, OBA #2614
L. Mark Bonner, OBA #14541
127 N.W. 10th St.
Oklahoma City, OK 73103
405-272-0200
405-272-1055 (fax)
Attorneys for Plaintiff

ATTORNEYS LIEN CLAIMED

JURY TRIAL DEMANDED

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2011, I electronically transmitted the attached document to the Clerk of Court using the ECF System for filing. Based on the records currently on file, the Clerk of Court will transmit a Notice of Electronic Filing to the following ECF registrants:

HALL, ESTILL, HARDWICK,
GABLE, GOLDEN & NELSON, P.C.
Jon Epstein, OBA # 13274
Chase Tower
100 North Broadway, Ste. 2900
Oklahoma City, OK 73102-8865
(405) 553-2828; (405) 553-2855 (F)
jepstein@hallestill.com

PIETRAGALLO, GORDON, ALFANO
BOSICK & RASPANTI, LLP
Clem C. Trischler, Esq.
Admission to be sought
The Thirty-Eighth Floor
One Oxford Centre
Pittsburgh, PA 15219
(412) 263-2000; (412) 261-5295 (F)
cct@pietragallo.com

/s/ L. Mark Bonner